ANDA 40-215 (10%)
40-216 (30%)

May 25, 1999

Akorn, Inc.
Attention: Syed J. Akhtar
72-6 Veronica Avenue
Somerset, NJ 08873

Dear Sir:

This is in reference to your abbreviated new drug applications dated October 11, 1996, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Sulfacetamide Sodium Ophthalmic Solution USP.

Reference is also made to your amendments dated November 9, 1998; February 26, March 8, April 19, April 26, and May 19, 1999.

We have completed the review of these abbreviated applications and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the applications are approved. The Division of Bioequivalence has determined your Sulfacetamide Sodium Ophthalmic Solution USP, 10% and 30%, are bioequivalent and, therefore, therapeutically equivalent to the listed drug (Sodium Sulamyd® Ophthalmic Solution, 10% and 30%, respectively, of Schering Corp.).

Under 21 CFR 314.70, certain changes in the conditions described in these abbreviated applications require approved supplemental applications before the change may be made.

Post-marketing reporting requirements for these abbreviated applications are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-40). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-40) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research